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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/783,362	02/20/2004	Shiping Wang	029714.00017	2424
79439 7590 09/02/2010 Arent Fox LLP and Cardinal Health, Inc. 1050 Connecticut Ave., N.W. Suite 400 Washington, DC 20036				
EXAMINER				
AHMED, HASAN SYED				
ART UNIT		PAPER NUMBER		
1615				
NOTIFICATION DATE		DELIVERY MODE		
09/02/2010		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/783,362

Applicant(s)

WANG ET AL.

Examiner

HASAN S. AHMED

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1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 June 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-29, 33, 34, 43-46, 48 and 49 is/are pending in the application.
- 4a) Of the above claim(s) 7-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-29, 33, 34, 43-46, 48, and 49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Receipt is acknowledged of applicants': (a) amendment and remarks, filed on 1 February 2010, and (b) response to notice of non-compliant amendment, filed on 11 June 2010.

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 27-29, 33, 34, 43-46, 48, and 49 remain rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,133,090 ("Modak") in view of U.S. Application No. 2002/0152538 ("McDevitt"), further in view of U.S. Patent No. 5,322,161 ("Shichman"), further in view of U.S. Patent No. 5,357,636 ("Dresdner").

Modak teaches an elastomeric body (reading on claims 27 and 43) with a coating comprising an antiinfective agent (reading on claims 27 and 43) comprising chlorhexidine or pharmaceutically acceptable salts of chlorhexidine (reading on claims 27 and 45) and a lubricating agent (see col. 2, lines 9-20). Examples 3 and 4 provide a coating free of starch (reading on claims 27 and 43).

The coating may further comprise a quaternary ammonium halide (see col. 4, lines 12-13) such as benzalkonium chloride (reading on claims 27, 29, 34, 45, and 49) (see col. 2, line 61).

The coating may further comprise biomedically acceptable polymers, such as polyurethanes and silicones (see col. 2, lines 65-66). Modak explains that polymers are used, "to minimize the possibility of lubricating agent being released from the glove surface and to provide lubricity due to the nature of the polymeric component." (See col. 3, lines 1-4).

The disclosed glove provides, "an effective antiviral amount of antiinfective agent such that an effective antiviral amount of the antiinfective agent is released within ten minutes of being exposed to a fluid...Preferably, the inner coating will provide substantially instantaneous release of the antiinfective agent..." (See col. 3, lines 9-16).

The Modak reference differs from the instant application in that it does not provide a coating on an outside surface of an elastomeric article, as required by amended claims 27 and 43; however the coating of an antimicrobial composition on the outside surface of an elastomeric article is known in the prior art (see Dresdner, Example 1). Sterile packaging of the elastomeric gloves was also known in the prior art (see Dresdner, col. 1, line 66). Dresdner further teaches use of chlorhexidine gluconate (see col. 27, line 41) and benzalkonium chloride (see col. 28, line 58) as antiseptic agents.

The Modak reference differs from the instant application in that it does not teach a process of extending antimicrobial activity.

McDevitt teaches an elastomeric glove (see paragraph 0054). The disclosed glove is comprised of:

- the antimicrobial agent of instant claims 27 and 43 (see paragraph 0030);

- the packaging of instant claims 27 and 43 (see paragraph 0189); and
- the moisture-resistant barrier container (e.g. film foil laminate) of instant claims 33 and 48 (see paragraph 0189).

Neither Modak nor McDevitt teach a desiccant, however use of desiccants in metal foil packaging was known in the art at the time the instant application was filed as evinced by Shichman (see col. 2, lines 49-51).

The reduced humidity and extended antimicrobial activity of instant claims 27 and 43 are an inherent property of foil packaging containing desiccant.

McDevitt explains that packaging the gloves is beneficial, "...in order to preserve any additives applied to the finger glove or otherwise to maintain the finger glove in a sterile environment." See paragraph 0189.

The references are silent with respect to the antimicrobial activity recited in instant claims 27 and 43. The prior art, as instantly claimed, discloses antimicrobial elastomeric articles packaged in foil containing desiccant (see above). Properties are the same when the structure and composition are the same. Thus, burden shifts to applicant to show unexpected results, by declaration or otherwise. *In re Fitzgerald*, 205 USPQ 594. In the alternative, the claimed properties would have been present once the composition was employed in its intended use. *In re Best*, 195 USPQ 433.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to disclose antimicrobial elastomeric articles packaged in foil containing desiccant, as taught by Modak in view of McDevitt, further in view of Shichman. One of ordinary skill in the art at the time the invention was made would

have been motivated to use such a process because it leads to preservation of additives (such as antimicrobial agent), as explained by McDevitt.

* * * * *

Response to Arguments

Applicants' arguments filed 1 February 2010 have been fully considered but they are not persuasive.

1. Applicants argue that Modak specifically teaches that the lubricating agent is preferably a modified corn starch. See remarks, page 11.

Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. In re Susi, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). See MPEP 2123. Examiner respectfully submits that Modak teaches corn starch as an optional (i.e. not required) ingredient (see col. 2, lines 56-60; examples 3 and 4).

2. Applicants argue, "Each embodiment and example described in Modak requires that the glove be coated with a slurry containing a non-adsorbent lubricating agent (i.e., a starch or powder), and an antiviral agent....All of the slurries described in Modak contain starch or powder lubricants such as cornstarch, hydroxyethylcellulose and zinc oxide. There is no disclosure or suggestion in Modak of gloves having antiviral inner coatings that are essentially free of powder and starch" See remarks, paragraph bridging pages 11 and 12.

Independent claims 27 and 43 recite, "...an elastomeric article that is essentially free of powder..." (emphasis added). Essentially free of powder is defined in the instant

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specification as less than about 2 mg of residue per glove (see [0033]). Applicants state that zinc oxide, hydroxyethylcellulose, and corn starch are powders (see pages 11 and 12). Of these, example 4 of Modak requires only hydroxyethylcellulose (i.e. zinc oxide is optional and thus not required) at a concentration of 2% of the antiinfective slurry. Dipping of the glove in a solution comprising 2% hydroxyethylcellulose will leave a residue of less than about 2 mg on the glove (i.e. 1 liter of water weighs 1kg; as such, a solution comprising about 2 ml hydroxyethylcellulose will contain about 0.002 mg hydroxyethylcellulose). As such, examiner respectfully submits that Example 4 of Modak meets the limitation "essentially free of powder" as the phrase is defined in the instant specification.

3. Applicants argue, "[p]roviding an antiseptic composition sandwiched between glove layers is not the same as providing a glove having an outer antiseptic coating, and Applicants submit that one skilled in the art would not modify the glove of Modak, which has an inner antiseptic coating, to provide an outer antiseptic coating thereon based on the disclosure of Dresdner." See remarks, page 13.

The instant specification defines "outer surface" as the portion of the glove that comes into contact with other objects, such as medical instruments (see [0034]); "inside surface", by contrast, is defined as the surface that comes into contact with the wearer's hand (see [0034]). Examiner respectfully submits that the outside surface of the inner layer of the Dresdner glove (e.g., the outside surface of item (2) of Fig. 1B) meets the instant specification's definition of "outer surface" since this surface comes into contact with other objects, such as medical instruments (see, e.g., col. 19, lines 59-67 and Fig

2A and 2B) and does not contact the wearer's skin. The instant claims do not preclude the extra layer which covers antiseptic composition. Dresdner explains that if an object piercing the glove contacts the antiseptic formulation before contacting the skin surface, this may immediately provide a protective treatment to the gloved individual so that the individual does not acquire a systemic infection from the infectious pathogen on the glove-puncturing object (see col. 14, liens 26-37). As such, a person of ordinary skill in the art reading the disclosure of Dresdner would be motivated to add an antiseptic composition to the surface of the glove that comes into contact with other objects, such as medical instruments.

* * * * *

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

★

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HASAN S. AHMED whose telephone number is (571)272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571)272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. S. A./
Examiner, Art Unit 1615

/Humera N. Sheikh/
Primary Examiner, Art Unit 1615